

## **REMARKS**

### **A. STATUS OF THE CLAIMS**

As a result of the present amendment, claims 1-54 are cancelled and new claims 55-109 are presented in the case for continued prosecution.

New claim 55 is directed to a composition including (a) an interferon polyalkylene oxide conjugate; and optionally including (b) an excipient, and (c) a buffer.

It is believed that new claims 55-98, directed to compositions comprising interferon conjugated to a polyalkylene polymer and methods of making said compositions, correspond to the invention of Group I, directed to cancelled claims 1-43.

It is believed that new claims 99-102, directed to methods of administering the composition of Group I, correspond to the invention of Group II, directed to cancelled claims 44-47.

It is believed that new claims 103-109, directed to methods of preparing a polyalkylene oxide-protein conjugate, correspond to the invention of Group III, directed to cancelled claims 48-54.

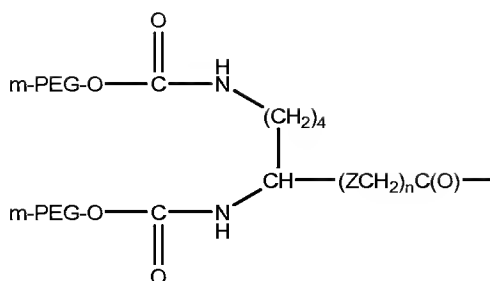
New claims 72 and 76, corresponding to cancelled claims 17 and 21, correct informalities found in sulfur-containing embodiments from “-CH<sub>2</sub>CH<sub>2</sub>SH-” to “-CH<sub>2</sub>CH<sub>2</sub>S-”. Those of ordinary skill in the art can appreciate that the recitation of “-CH<sub>2</sub>CH<sub>2</sub>SH-” means “-CH<sub>2</sub>CH<sub>2</sub>S-” because sulfur forms two covalent bonds. No new matter has been added.

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### **B. RESTRICTION REQUIREMENT**

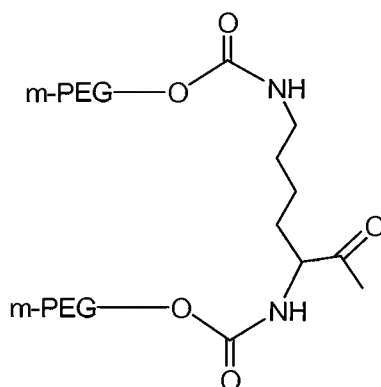
In response to the restriction requirement, Applicants elect Group I, new claims 55-98, drawn to a composition comprising IFN conjugated to a polyalkylene polymer and methods of making said composition.

Applicants further elect an interferon-polyalkylene oxide conjugate including a branched polyalkylene oxide polymer. The elected branched polymer is one embodiment of the formula described in claim 74, which is reproduced as follows:



wherein (n) is zero.

The elected branched polymer has the structure:



This response is made with traverse. It is respectfully urged that the claims of Group I (new claims 55-98), Group II (new claims 99-102) and Group III (new claims 103-109) be examined together. Reconsideration is respectfully requested.

The Examiner indicated that the inventions are distinct. On the contrary, the products of Group I are necessarily used by the methods of Groups II and III. Accordingly, Applicants urge that there would not be an undue burden upon the Examiner to search and consider Groups I, II and III at the same time.

The Examiner indicated that the inventions do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2 they lack the same special technical feature. However, the technical feature of the present invention is described in new claims 55-98 in Group I. Specifically, the methods of administering in Group II, new claims 99-10, and the methods of preparing the conjugate in Group III, new claims 103-109, necessarily utilize the product in elected Group I. Thus, Groups I, II and III do relate to a single general inventive concept under PCT Rule 13.1 by sharing the same or corresponding special technical features, and the search directed to non-elected Groups II and III will overlap a search strategy directed to

the elected Group I. Accordingly, Applicants urge that there would not be an undue burden upon the Examiner to search and consider Groups I, II and III at the same time.

The Examiner's attention is also alerted to the fact that the International Bureau made no lack of unity rejection during the international phase. To make a holding of lack of unity of invention at this stage would be inconsistent with PCT Rule 13.1.

In addition, the Examiner has the discretion to prosecute all of the pending claims in a single patent application. In fact, “[I]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” (Emphasis added; Manual of Patent Examining Procedure, § 803, second paragraph).

Thus, for reasons of efficiency in prosecution and searching, it is urged that Groups I-III be examined together and the Examiner is respectfully requested to reconsider and withdraw the present Restriction Requirement.

### C. **SPECIES ELECTION**

The Examiner indicated that cancelled claims 1, 20 and 33 are generic. It is believed that the corresponding new claims 55, 76 and 88 are generic.

The Examiner required a species to be selected from each of (1) buffers, (2) excipients, (3) surfactants, (4) activated polyethylene glycols, and (5) terminal reactive moieties listed on cancelled claim 43, on pages 4 and 5 of the Office Action. In response to the requirement to elect species, Applicants elect to prosecute the following in the event that no generic claim is finally held allowable:

(1) Buffer: sodium acetate

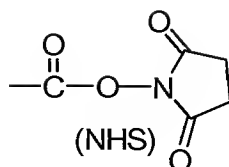
(2) Excipient: mannitol

(3) Surfactant: polyethylene glycol

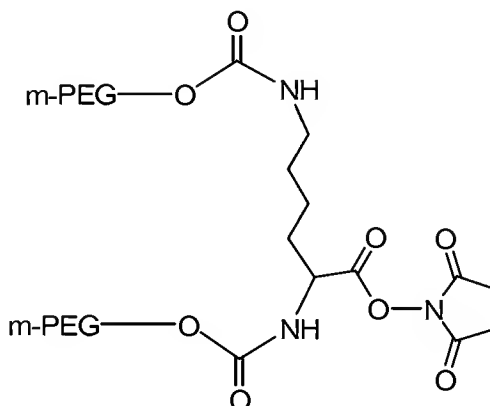
(4) Activated polyethylene glycol from new claim 96 (cancelled claim 41):



(5) Terminal reactive moiety from new claim 98 (cancelled claim 43):



With respect to the activated branched moiety including the terminal reactive moiety, it thus has the structure:



It is believed that new claims 55-71, 74-94, and 98 read on the elected species.

#### **D. REJOINDER**

Applicants reserve the right to request rejoinder of all appropriate claims removed by the Examiner.

#### **E. FEES**

This response is being filed within the shortened period for response. The due date of November 21, 2009 falls on a Saturday and thus the period for a timely response extends to Monday, November 23, 2009. No further fees are believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

/Hyun Soon Cho /  
Hyun Soon Cho  
Recognition No. L0306

LUCAS & MERCANTI, LLP  
475 Park Avenue South  
New York, New York 10016  
Phone: 212-661-8000  
Fax: 212-661-8002